Remarks

Amendments to the Claims

The amendments do not add new matter. Claim 2 is amended to delete the recitation in step (i) "or in the absence of said test compound," which is now recited in new claim 24. Claim 2 also is amended to recite that the NPEPPS polypeptide comprises the amino acid sequence SEQ ID NO:2 and to recite an identifying step. Recitation of SEQ ID NO:2 is supported on page 8, line 11. Recitation of the identifying step is supported in the discussion of screening methods on page 30, line 9 to page 34, line 24. New claim 24 parallels claim 2.

Rejection Under 35 U.S.C. § 112 ¶ 1 (enablement)

Claim 2 is rejected under 35 U.S.C. § 112 ¶ 1 as not enabled. Applicants respectfully traverse the rejection. The arguments below apply with equal force to new claim 24.

The enablement requirement of 35 U.S.C. § 112, first paragraph states that a patent specification must teach a person skilled in the relevant art how to make and use the invention claimed. Whether a specification enables a claimed invention is a question of law based on underlying factual findings. *In re Vaeck*, 947 F.2d 488, 495, 20 U.S.P.Q.2d 1438, 1444 (Fed. Cir. 1991). The proper standard for determining whether the present specification meets the enablement requirement is whether any experimentation which may be needed to practice the methods claim 2 is undue or unreasonable. *In re Wands*, 858 F.2d 731, 736-37, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

The PTO has the initial burden to establish a reasonable basis to question the enablement provided in the specification. *In re Wright*, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). The PTO has not met this burden. On page 3, second paragraph, the Office

Action contends that "one [of] ordinary skill in the art would not conclude that merely identifying compounds capable of modulating NPEPPS polypeptide activity would be sufficient as a 'useful' treatment . . . ." In the paragraph bridging pages 3 and 4 the Office Action states that "upregulation (e.g. higher level) or downregulation (e.g. lower level) of a particular protein for a particular disease does not warrant a causal-link that modulation of said particular protein is the key for successful treatment." The Office Action also faults the specification for not providing treatment data.

The rejection is based on an incorrect construction of claim 2. Claim 2 does not require that the identified compound ***be*** useful for treating the recited disease types. Rather, claim 2 is directed to a method of ***screening*** for therapeutic agents useful in treatment; *i.e.*, the identified test compounds need only be of ***potential*** use in disease treatment. The expression data presented in the specification is adequate for one of skill in the art to assess test compounds for their ability to regulate NPEPPS protein activity for the purpose of screening them as potential therapeutic agents.

Please withdraw the rejection.

Rejection Under 35 U.S.C. § 112 ¶ 1 (written description)

Claim 2 is rejected under 35 U.S.C. § 112 ¶ 1 as insufficiently described. To advance prosecution, claim 1 and new claim 24 recite that the NPEPPS polypeptide comprises "the amino acid sequence SEQ ID NO:2."

Please withdraw the rejection.

Rejection Under 35 U.S.C. § 112 ¶ 2

Claim 2 is rejected as indefinite under 35 U.S.C. § 112 ¶ 2. Applicants respectfully traverse the rejection.

First, the Office Action contends that it is not clear whether steps (i) and (ii) are the same because step (i) recites "or in the absence of said test compound." To advance prosecution, this option has been deleted from claim 2 and is now recited in new claim 24.

Second, the Office Action contends that claim 2 is not a complete claim because "no results, i.e. higher activity or lower activity is linked to a 'useful treatment.'" As an initial matter, as explained above in connection with the enablement rejection, claim 2 does not require "useful treatment." To advance prosecution, claim 2 is amended to recite a step of "identifying the test compound as useful in the treatment of the disease if it regulates the activity of the NPEPPS polypeptide." New claim 24 also recites this step.

Please withdraw the rejection.

Rejections Under 35 U.S.C. § 102(b)

Claim 2 is rejected as anticipated under 35 U.S.C. § 102(b) by Yang (WO 01/46443) and by Fontana (WO 97/38114). Applicants respectfully traverse the rejections.

Anticipation under 35 U.S.C. § 102 requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Thus, to determine whether a claim is anticipated by a prior art reference, one must first recognize each element of the invention recited in the claim and determine whether the prior art reference discloses the same element(s). *Kalman v. Kimberly-Clark Corp.*, 218 U.S.P.Q. 781,

789 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). One must then determine whether the prior art reference describes the invention sufficiently so that one of skill in the art could make the invention. *In re LeGrice*, 133 U.S.P.Q. 365, 373-74 (C.C.P.A. 1962). Claim 2 and new claim 24 are directed to a method of screening for therapeutic agents useful in the treatment of the following set of disease types: dermatological diseases, endocrinological diseases, metabolic diseases, gastroenterological diseases, muscle-skeleton diseases, neurological diseases, respiratory diseases, inflammation and urological diseases. Neither Yang nor Fontana anticipates this subject matter.

Yang

Yang does not explicitly teach a method of screening for therapeutic agents useful in the treatment of any of the disease types recited in claims 2 and 24. Yang discloses 28 proteins; the protein comprising SEQ ID NO:23 is relevant. Yang discusses use of the proteins in screening methods and as useful for treating several disease types. See page 12, line 21 to page 14, line 3; page 40, lines 12-22; page 28, lines 25-28; page 41, lines 18-22; page 41, line 28 to page 44, line 34. Yang contains no disclosure associating any of the disease types with any one in particular of the 28 proteins. Thus, Yang does not explicitly teach the subject matter of claim 2 or claim 24.

Nor does Yang inherently teach this subject matter. To establish inherency, extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1759 (Fed. Cir. 1991) (emphasis added). In fact, Yang teaches one of skill in the art how to find out whether a protein can be used to diagnose a particular disease state. See page 59, lines 25-33. The

disclosure of Yang is not such that a person of ordinary skill would recognize a description of a method of screening for therapeutic agents useful in the treatment of dermatological diseases, endocrinological diseases, metabolic diseases, gastroenterological diseases, muscle-skeleton diseases, neurological diseases, respiratory diseases, inflammation, or urological diseases.

Moreover, Yang does not present any supporting expression data supporting an association of any of the disclosed 28 proteins with any tissue relating to the disease types recited in claims 2 and 24 or with any disease state. Without such data, one of skill in the art could not use any of those proteins – including the protein comprising SEQ ID NO:23 – in a method of screening for therapeutic agents useful in the treatment of the disease recited in claims 2 and 24. In contrast, the present specification provides expression data which support each of the recited disease types.

Fontana

Fontana does not explicitly teach a method of screening for therapeutic agents useful in the treatment of any of the disease types recited in claims 2 and 24. On page 10, 5th full paragraph, Fontana discusses the apoptotic activity, but this is of the disclosed proteins, not a compound which modulates the activity of the disclosed proteins. The paragraph bridging pages 51 and 52 mentions treating psoriasis and obesity based on antiproliferative activity of some disclosed compounds, but there is no data correlating expression of the proteins with tissues relevant to these disorders. On page 70 Fontana states "[a] single PSA transcript of 2.5 kb is detectable in all organs examined (heart, brain, spleen, lung, liver, skeletal muscle, kidney, testis) suggesting that its expression is widely distributed." However, the results section in Fontana, including this statement, is in the present tense and there are no tabular or graphic depictions of data; thus, it is not clear that the experiments were actually carried out. Because the disclosure

of Fontana is not such that a person of ordinary skill would recognize a description of a method of screening for therapeutic agents useful in the treatment of the recited disease types, Fontana does not inherently anticipate the subject matter of claims 2 or 24.

Moreover, without expression data, one of skill in the art could not use the proteins of Fontana in a method of screening for therapeutic agents useful in the treatment of the disease recited in claims 2 and 24. Again, in contrast, the present specification provides expression data which support each of the recited disease types.

Neither Yang nor Fontana discloses or enables the subject matter of claims 2 and claim 24. Please withdraw the rejections.

Respectfully submitted,

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